

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons which follow.

Claims 19-23 are requested to be cancelled.

Claims 1-2, 6, 8, 25-27, and 30 are currently being amended.

Claims 31-36 are being added.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, are presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-18 and 24-36 are now pending in this application. Claim 11 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Claims 1-4, 6-12, 26, 27, and 30 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Sablotsky. (U.S. Patent No. 4,994,267). Claims 5, 13-25, 28, and 29 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Sablotsky in view of Miranda et al. (U.S. Patent No. 5,474,783). Reconsideration is requested.

Claim 11 is Definite

Claim 11 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. According to the PTO, the phrase "substantially only" is unclear. Applicants respectfully disagree. The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. Claim 11 recites that the at least two polymer polymers contain substantially only the first and second acrylic-based polymers. This language clearly informs the public that in claim 11 the first and second acrylic based polymers are substantially the only polymers in the dermal composition. The general

guidelines contained in the specification set out the scope of this language. *See, e.g., In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975); *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988). Accordingly, the rejection should be withdrawn.

Claims 1-4, 6-12, 26, 27, and 30 are Patentable Over Sablotsky

Claims 1-4, 6-12, 26, 27, and 30 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Sablotsky. The claims have been amended herein to recite that the composition includes “a first acrylic-based polymer having substantially no functional groups and a first solubility parameter.” Such a composition is neither shown nor taught by Sablotsky. Sablotsky teaches the blending of two functional acrylic-based polymers. Acrylic-based functional polymers are defined as polymers that have reactive chemical groups, including carboxyl, epoxy, and hydroxy groups, which modify the acrylic-based polymers directly or provide sites for further reactions. The present invention, as now defined in claim 1, teaches use of non-functional acrylic-based polymers used in conjunction with at least one other acrylic-based polymer. Non-functional acrylic-based polymers are defined as those polymers that have no or substantially no functional reactive moieties present in the acrylic. These are generally acrylic esters, which can be copolymerized with other monomers, which do not have functional groups, such as vinyl acetate or acrylic acid.

It is well settled that an invention lacks novelty under 35 U.S.C. § 102 *only* if each and every element of the claim is described or disclosed, either explicitly or inherently, in a single prior art reference. *Finnigan Corp. v. International Trade Com'n*, 180 F.3d 1354, 1365 (Fed. Cir. 1999). In fact, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). Here, Sablotsky does not disclose or suggest the instantly claimed invention. For at least these reasons, claims 1-18 and 24-36 are patentable over Sablotsky as Sablotsky does not disclose or suggest a composition that includes a polymer composition of two or more polymers which includes “a first acrylic-based polymer having substantially no functional groups and a first solubility parameter” and “a second acrylic-based polymer having a second functionality.”

Claims 5, 13-25, 28, and 29 are Patentable Over the Prior Art of Record

Claims 5, 13-25, 28, and 29 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Sablotsky in view of Miranda et al.

As set forth above, Sablotsky does not disclose or suggest a composition that includes a polymer composition of two or more polymers which includes “a first acrylic-based polymer having substantially no functional groups and a first solubility parameter” and “a second acrylic-based polymer having a second functionality.” There is nothing in Miranda that overcomes this deficiency in Sablotsky. Miranda does not disclose or suggest a polymer composition which includes “a first acrylic-based polymer having substantially no functional groups and a first solubility parameter” and “a second acrylic-based polymer having a second functionality.”

Furthermore, there is no motivation, in the references or elsewhere, to modify any of the references of record to arrive at the instantly claimed invention. The use of at least one non-functional acrylic-based polymer provides the ability to control the flux, and particularly allows the flux to be selectively increased as shown in the Application examples. Flux is defined as the percutaneous absorption of drugs through the skin. Figs. 1-4 provide evidence that by providing an amount of non-functional acrylic in the dermal composition, the solubility of the drug in the polymer composition can be controllably reduced, and therefore yields a greater thermodynamic driving force, which increases the flux of the drug across the skin. These as well as other aspects of the invention as now defined in the claims as amended clearly distinguish over Sablotsky and Miranda, either alone or in combination.

Until the present invention, it was not appreciated by the person having ordinary skill in the art that by selecting and combining two or more acrylic-based polymers that the solubility of a drug in a transdermal composition and hence its rate of delivery from the composition could be controlled. Neither Sablotsky, nor Miranda, either alone or in combination, disclose or suggest the subject matter of claims 1, 26 and 30. Since claims 2-18,

22-24 and 27-29 depend from these claims, for at least this reason these claims are also patentable over Sablotsky and Miranda.

Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By



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